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09/524,113	03/13/2000	Jitendra P Patel	6475.US.O2	6413

23492 7590 01/14/2004

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EXAMINER

BAHAR, MOJDEH

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 01/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.





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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Paper No. 123003

Application Number: 09/524,113  
Filing Date: March 13, 2000  
Appellant(s): PATEL ET AL.

**MAILED**  
**JAN 14 2004**  
**GROUP 2900**

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Martin L. Katz  
For Appellant

**EXAMINER'S ANSWER**

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This is in response to the appeal brief filed 15 October 2003.



**(1) *Real Party in Interest***

A statement identifying the real party in interest, Abbott Laboratories, is contained in the brief.

**(2) *Related Appeals and Interferences***

A statement indicating there are no related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

**(3) *Status of Claims***

The statement of the status of the claims contained in the brief is correct.

**(4) *Status of Amendments After Final***

The appellant's statement of the status of amendments after final rejection contained in the brief is incorrect.

On page 2 of the Appeal Brief, Appellant's representative indicates that "Claims 1, 3, 7-12 and 9, **as presently amended**, are set forth in the Appendix." Please note that there is no amendment accompanying the Appeal Brief and although claim 1 has been amended 4 times and claims 3, 7, 9, 11 and 16-18 have been amended once, all claims had already been amended by the time of issuance of the final rejection of 3 May 2003.

**(5) *Summary of Invention***

The summary of invention contained in the brief is deficient because applicant states that "the present invention is directed to a composition **consisting of** a fibrate dissolved in at least one oil with one specified emulsifier." Note that claims 1, 3 and 7-12 are drawn to a composition **consisting essentially of** a fibrate dissolved in at least one oil with one emulsifier



Art Unit: 1617

selected from a Markush group recited in claim 1. **Note that “consisting of,” and “consisting essentially of” are not equivalent of one another.** Further note that the pending claims recite many different possibilities for the emulsifier in a Markush format, not one specific emulsifier.

Appellant then enumerates the advantages of its composition, i.e., increased drug solubility, oral bioavailability and half-life. Note that these advantages cannot be stated, they must be shown.

**(6) Issues**

The appellant's statement of the issues in the brief is correct.

**(7) Grouping of Claims**

The rejection of claims 1, 3, 7-12 and 19 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

**(8) Claims Appealed**

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(9) Prior Art of Record**

5,645,856

Lacy

7-1997

**(10) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

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Claims 1, 3, 7-12 and 19 are rejected under 35 U.S.C. 103(a). This rejection is set forth in prior Office Action, and is reproduced herein below.



Art Unit: 1617

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3, 7-12 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lacy et al. (USPN 5,645,856).

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Lacy et al. (USPN 5,645,856) teaches a carrier system for a hydrophobic drug (including finofibrate) composition comprising (a) a digestible oil (including soybean oil, coconut oil, corn oil, palm oil, cottonseed oil, olive oil, safflower seed oil); (b) a pharmaceutically acceptable



Art Unit: 1617

surfactant comprising a hydrophilic (including phospholipids, polyethylene sorbitan fatty acid derivatives, castor oil or hydrogenated ester castor oil ethoxylates, fatty acid ethoxylates, alcohol ethoxylates, polyoxyethylene-polyoxypropylene co-polymers and block co-polymers) and a lipophilic surfactant (including propylene glycol), see in particular col. 3, lines 38-67, cols. 5-9 and col. 11, lines 22-23, see col. 21 example 6, lines 21-31.

Lacy et al. (USPN 5,645,856) does not particularly teach an emulsion composition consisting essentially of fenofibrate with the claimed oil and emulsifiers.

It would have been obvious to one of ordinary skill at the time the invention was made to employ fenofibrate in an emulsion composition consisting essentially of the recited oils and emulsifier.

One of ordinary skill in the art would have been motivated to incorporate any of the named hydrophobic drugs in Lacy et al. (USPN 5,645,856) in Lacy's pharmaceutical carrier because Lacy teaches a pharmaceutical combination composition that includes a hydrophobic drug, oil and surfactants (both lipophilic and hydrophilic).

**(11) Response to Argument**

Appellant's arguments have been fully considered but they are not persuasive. Appellant first argues that Lacy does not render the claims unpatentable because Lacy requires surfactants that are different in character than the specifically claimed emulsifiers herein. Note that Lacy enumerates certain hydrophilic surfactants that are particularly claimed herein, e.g.,

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phospholipids, polyethylene sorbitan fatty acid derivatives, castor oil or hydrogenated ester castor oil ethoxylates, fatty acid ethoxylates, alcohol ethoxylates, polyoxyethylene-polyoxypropylene co-polymers and block co-polymers (see instant claims 19, 1, 7). Note also



that the lipophilic surfactant, e.g. propylene glycol, taught by Lacy is also claimed herein (see the instant claim 12). Therefore both the hydrophilic and the lipophilic surfactants of Lacy read on the instant claims.

Appellant then argues that Lacy teaches away from the instant composition because Lacy discloses a carrier for hydrophobic drugs comprising a digestible oil and a pharmaceutically acceptable surfactant. Appellant argues that the surfactants taught in Lacy possess particular qualities, e.g., the hydrophilic surfactant component is such that it does not inhibit the lipolysis of oil not required/claimed herein. Appellant further states that the emulsifiers used in the present invention do not exhibit or demonstrate the property of not essentially inhibiting the lipolysis of oil. Appellant further argues that this property is an important property of the prior art composition. Note that as discussed above, some of the hydrophilic and lipophilic surfactants of Lacy are specifically recited as suitable surfactants in the instant claims. Given that a compound and its properties CANNOT be mutually exclusive, the surfactants of Lacy, read on the instant claims 1,7,12, and 19. The instant claims are therefore obvious over the Lacy reference as set forth herein above.

For the above reasons, it is believed that the rejections should be sustained.

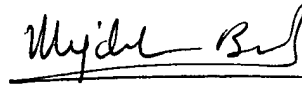
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Application/Control Number: 09/524,113  
Art Unit: 1617


Page 7

Respectfully submitted,



Mojdeh Bahar, J.D.  
January 6, 2004

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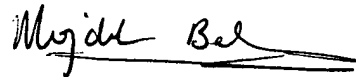
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Application/Control Number: 09/524,113  
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Page 7

Respectfully submitted,




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